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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,683	01/20/2004	Thomas E. Broome	1001.1720101	5270
28075	7590	03/24/2008	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			SEVERSON, RYAN J	
			ART UNIT	PAPER NUMBER
			3731	
			MAIL DATE	DELIVERY MODE
			03/24/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/762,683	<b>Applicant(s)</b> BROOME ET AL.	
	<b>Examiner</b> Ryan Severson	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 08 January 2008.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-36 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-36 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 20 January 2004 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the proximal section" in lines 6, 8, and 11. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 4-11, 22, and 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Vale et al. (2002/0058963).** Vale reference discloses the invention substantially as claimed in figures 13-17. For example, Vale discloses an elongated tubular member (70) with a proximal segment, a distal segment (71), and an inner lumen (see figure 13). Vale also discloses a dilator tip (50) inserted into part of the distal segment (see figure 15). The dilator tip has an outer diameter greater than the

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inner diameter of the distal segment (see figure 13). By pulling the tip (50) proximally, the distal segment of the tubular member is expanded (compare distal segment 71 in figures 13 and 15). The dilator tip has a generally circular cross section. The dilator tip has a proximal section (see figures in "Response to Arguments" section below), a distal section, and an inner lumen (see figures 13 and 15) that passes there through. The proximal section fits tightly within the distal segment (see figure 15). The distal section of the tip is tapered toward its distal end (see figure 13). The tubular member can expand to encompass an intravascular filter (see figure 17). The device can be used over a guidewire (25, see figure 16). The elongated tubular member can be used in a single operator exchange operation (see paragraph 73). Vale reference also discloses an embolic protection filter (2) disposed about an elongated wire (25) wherein the dilator tip (50) is capable of engaging a stop (the "hub" at the proximal end of the filter directly on the guidewire, see figure 15). The distal segment of the elongated tubular member is formed of an elastic material, which allows it to expand to take in the filter and the dilator tip without permanent deformation (as in figure 15).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. **Claims 2 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (2002/0058963) in view of Nilsson (5,873,851).** Vale reference does not disclose the proximal segment of the tubular member varies in thickness along its length. Attention is drawn to Nilsson reference, which teaches the wall thickness of a tubular member can have varying wall thickness (see column 5, lines 9-19) to provide a more flexible and resilient central section to assist in navigation through tortuous lumens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the wall thickness of the proximal segment of Vale reference along its length to provide a more flexible and resilient central section to assist in navigation through tortuous lumens.

7. **Claims 3, 12, 14-21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (2002/0058963) in view Salahieh et al. (2004/0127936).** Vale reference does not disclose a braid in the distal segment. Attention is drawn to Salahieh reference, which teaches a tubular member may have a braid in its distal end (see paragraph 18) to impart flexibility to the distal portion while maintaining axial stiffness. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the braid of Salahieh in the distal end of the tube of Vale to impart flexibility to the distal portion while maintaining axial stiffness.

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8. **Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (2002/0058963) in view of Salahieh et al. (2004/0127936) as applied to claim 12 above, and further in view of Nilsson (5,873,851).** The combination of Vale and Salahieh references does not disclose the proximal segment of the tubular member varies in thickness along its length. Attention is drawn to Nilsson reference, which teaches the wall thickness of a tubular member can have varying wall thickness (see column 5, lines 9-19) to provide a more flexible and resilient central section to assist in navigation through tortuous lumens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the wall thickness of the proximal segment of Vale in view of Salahieh reference along its length to provide a more flexible and resilient central section to assist in navigation through tortuous lumens.

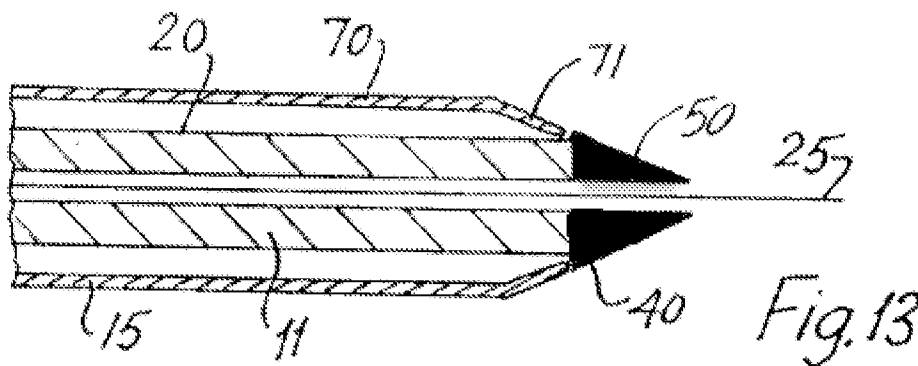
### ***Response to Arguments***

9. Applicant's arguments filed 08 January 2008 have been fully considered but they are not persuasive.

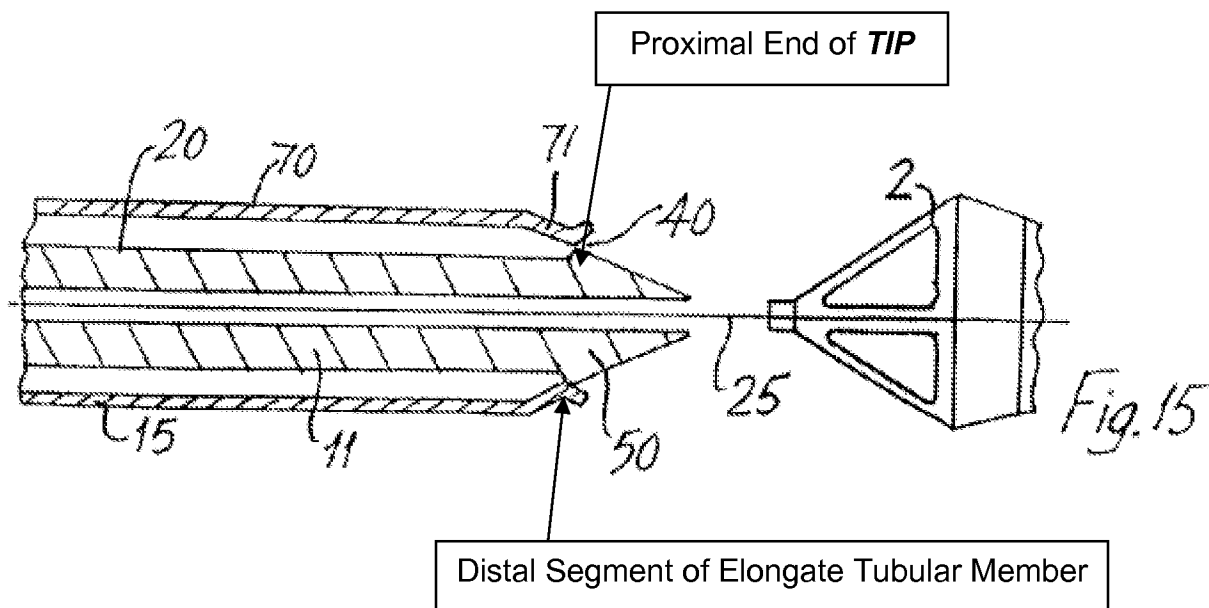
10. As an initial matter, applicant begins the arguments with the assertion that claims 1-36 have been rejected under 35 U.S.C 102 as being anticipated by Vale. However, as clearly set forth in the previous rejection, which is also repeated above, this is entirely untrue. Only claims 1, 4-11, 22, and 25-36 were rejection under the provisions of 35 U.S.C. 102(b).

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11. Further, applicant argues that the "arrowhead portion" is the distal portion of the catheter of Vale, and therefore does not meet the limitations of the claims. Examiner turns applicants attention to their own claims, in which it is recited the medical device comprises "a dilator **TIP**" (emphasis added) and not a "dilator catheter." In the figure once again reproduced below, the **TIP** of Vale reference has been shaded by the examiner for complete clarity.



12. The claim next requires that the "dilator **TIP**" has a proximal end. Once again, the **TIP** has proximal and distal portions, with the proximal portion being the portion with the greatest diameter (as set forth in the reproduced figure below) that is larger in diameter than the inner diameter of the distal segment of the elongated tubular member as required by the claims.



13. As can be clearly seen above, the proximal end of the **TIP** deforms the distal segment of the elongate tubular member because the proximal end has a greater diameter than the inner diameter of the distal segment.

14. Therefore, applicant's arguments based on the diameter of the *catheter* are not persuasive because examiner at no point has used the diameter of the catheter (11) in the rejections. Again, to be perfectly clear, applicant claims a **TIP** and not a catheter. As clearly shown in the figures above, the **TIP** of Vale has the structure as required in the claims.

15. Further, at pages 12 and 13 of the response filed, applicant recites paragraphs in Vale to support their argument. However, paragraphs 85 and 90 are drawn to a different embodiment than that set forth in the rejection, and therefore those arguments are moot. Paragraph 93 shows specific dimensions, again, of the centering *catheter*, and not the **TIP**.



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16. Paragraph 91, if applicant reads the paragraph carefully, further supports the rejection set forth by the examiner even though a different embodiment is used again. As applicant has underlined, the largest **outer** diameter ( $d_5$ ) of the distal end 50 is **equal** to the **outer** diameter ( $d_4$ ) of the catheter 60. If the two structures have the same **outer** diameters, then the inner diameter (which is inherently smaller than the outer diameter) of the catheter 60 **must** be smaller than the outer diameter of the distal end.

### ***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

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20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731